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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/479,783	01/07/2000	STANLEY T CROOKE	ISIS-4313	3541
34138	7590	05/18/2004		
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508				
			EXAMINER MCGARRY, SEAN	
			ART UNIT 1635	PAPER NUMBER

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/479,783

Applicant(s)

CROOKE, STANLEY T

Examiner

Sean R McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78-81, 93-102 and 106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 78-81, 93-102, and 106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/05/04 has been entered.

The rejections of record have are withdrawn, but see new grounds of rejection below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 78-81, 93-102 and 106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to read (or depend from claims that have been amended to read [it is noted that the claims originally read as currently amended]) "A double stranded RNA substrate". The specification does not provide a specific definition for this term. It is unclear for example what the claimed compound is a substrate for, for example. One in the art would not be apprised of the scope or the metes and bounds of

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the invention if he does not know what the meaning of this term may be. If one does not know what the substrate is for, how can one know what the metes and bounds of the invention is, for example? Is the invention a substrate for a double stranded RNA, for example?

Claims 78-81, 93-102 and 106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is based on the substrate for a dsRNase from T24 cells. The structure of the dsRNase has not been disclosed. The claimed invention is drawn to a "double stranded RNA substrate". The scope of the claimed invention is vastly wider than a substrate for a particular dsRNase, for example. The specification, as filed describes particular 2' methoxy modifications with RNA gaps (See Figure 1, for example) that allowed the function of acting as a substrate for the RNase from T24 cells. The scope of substrates disclosed in the instant specification is therefore narrow. The claimed invention is drawn to dsRNA substrates with modifications that provide for increased hybridization and/or increased nuclease stability while allowing the dsRNA substrate to act as a "substrate". It is noted that no other substrate function other than the specific dsRNase substrate function has been disclosed in the instant specification. It is noted that the specification does not, for example, indicate any particular functional

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characteristics [substrate functions, for example] that are coupled with a known or disclosed correlation between function and structure. The specification does not disclose the structure of the specific dsRNase used to determine the functionality of the specific substrate disclosed in the instant specification for example. As is noted in the instant specification, RNase H is very sensitive to structural alterations in antisense oligonucleotides (see page 2, for example). There is no indication that dsRNases as a class would be non-effected by chemical modifications, for example. The instant invention, for example, reads on double stranded RNA substrates for any dsRNase protein. The instant specification provides no structure function relationship for any of these potential dsRNases and any particular modification that may or may not allow a dsRNA to function as a substrate for any particular dsRNase. Furthermore, it is not so clearly described what the function of substrate may be, for example. The instant specification describes a specific RNases that acts to cleave a substrate. The instant claims are not so limited but embraces any conceivable function of a substrate, for example. To satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 96, 98, 99, and 100 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohtsuka et al [US 5,013,830, cited by applicant].

Ohtsuka et al have disclosed in Table 5, for example double stranded oligonucleotides that comprise double stranded RNA portions. The compounds include one oligonucleotide that comprises both DNA and RNA portions. The RNA/DNA oligonucleotide hybridizes to an RNA oligonucleotide. Since RNA:RNA hybridizations are stronger than RNA:DNA hybridizations one can reasonably interpret such modification to be a modification that increases the affinity of an oligonucleotide [all DNA as opposed to RNS/DNA, for example] to a complementary oligoribonucleotide. The compound also includes 2'-O-Me modifications which increase resistance to nucleases.

Claims 78, 94, 95, 99, and 101 are rejected under 35 U.S.C. 102(b) as being anticipated by Froehler et al [US 5,256,775, cited by applicant].

Froehler et al disclose RNA oligonucleotides (see column 4, for example) that are 3-50 nucleotides in length which contain modification on the 3' and 5' ends to protect from nucleases where the central portion of the oligonucleotide is phosphodiester linked (see column 5, for example). Since these oligonucleotides are disclosed for use to hybridize and inhibit an RNA target such as mRNA (see column 1 and 12, for example), the instantly claimed invention has been disclosed.

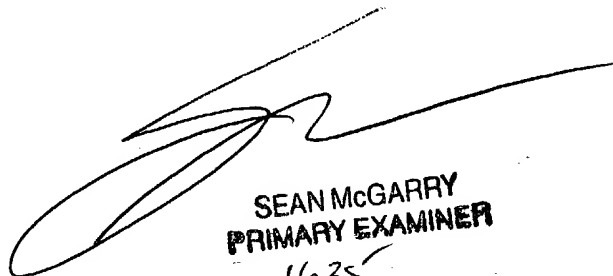
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SRM



SEAN MCGARRY
PRIMARY EXAMINER
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